CYANAMID

8EHQ-95-13301

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American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470

H. Michael D. Utidjian, M.D.
Corporate Medical Director

(A)

December 27, 1994
Study #94-144

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

Attention: Section 8(e) Coordinator

COMPANY SANITIZED

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), of results of an eye irritation screening study in rabbits communicated by memo on December 19, 1994. We have conducted this study on a 20% wettable powder formulation of a research material, which is identified as XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX also known as XXXXXXXXXX, and generically designated as a substituted azoxycyanide.

Compound Structure

XXX

1. Eye Irritation Screening Study in Rabbits Study 94-144

Two albino rabbits were exposed to the test material (100 mg/eye) without washing. The test material was found to be corrosive to the eye by 72-hour posttreatment.

We are currently evaluating the significance of these results. This material is under consideration for research and development as a fungicide and is a research chemical.

If further information is required, please contact K.A. Traul, Ph.D. at 609-799-0400, Ext. 2701.

Sincerely,

K.A. Traul for H.M.D.U.

H. Michael D. Utidjian,M.D.
Corporate Medical Director

TSCA24.94

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Support Information for Confidentiality Claims

TSCA 8(e) Submission on
Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

1. For what period of time do you assert this claim of confidentiality? Explain why the information should remain confidential until such event or time.

Confidentiality is claimed for a period of 10 years from the date of submission pending finalization of the applications for a patent on the test material and the process for its synthesis. It is suggested that the generic name substituted azoxycyanide be used in reference to this 8(e) submission. The period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D organization to protect the confidentiality of its key resource library of chemicals.

2. Have there been any confidentiality determinations made by the EPA, other Federal agencies or courts in connection with this information?

No.

3. Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information.

Information regarding the name and structure have not been disclosed to persons outside the company. At such time as patents are issued for the structure and the processes for synthesis of the material we do not plan to disclose such information to persons outside the company who would not be under an agreement of confidentiality regarding such information. Such persons would include laboratory or field personnel conducting studies with this material under contract to the company or expert consultants we may retain. Other persons outside the company will become informed after the above referred patents are obtained and our evaluation of the material is complete.

4. Briefly describe any physical or procedural restrictions within the company relating to the use and storage of the information you are claiming confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves the company.

The information has been given to only those individuals with a need to know. The information is considered "company confidential" and all employees who have access to this information are required to keep it confidential. Employees who have access to this information have signed confidentiality statements with regard to any such proprietary information.

5. Does the information claimed as confidential appear or is it referred to in any of the items listed below?

- advertising or promotional materials for the chemical or the end product containing it ;
- safety data sheets or other such materials for the chemical or the end product containing it;
- professional or trade publications;
- any other media available to the public or to your competitors:

If you answered yes to any of the above questions, you must indicate where the information appears and explain why it should, nonetheless, be treated as confidential.

No.

The information that is to be held confidential about the chemical structure and name may appear in a Material Safety Data Sheet prepared by the company for distribution to company personnel and contracted cooperators who are involved in the technical evaluation of the material in various field trials. Such persons will have signed confidentiality agreements.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position?

Disclosure of this information, prior to issue of the patents for the material and the processes for synthesis would jeopardize the proprietary nature of the material and would potentially cause the company to lose the advantage currently available though the fact that this information is not available to the competition in this market. The company is synthesizing and filing patents on analogs of this chemistry. Release of the information requested to be held confidential would aid competitive companies in analog synthesis. The technical attributes are still under investigation for this compound and the analogs, which may possess more favorable toxicologic characteristics. Additional use patents have also not yet been filed. Disclosure could jeopardize our patent positions in foreign countries. Although patent protection is guaranteed in the U.S. by FIFRA, there is no guarantee of protection in other countries. Further, misinterpretation or misrepresentation of these data could cause undue alarm to our customers and, thereby, damage our potential customer base. The period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D chemical organization to protect the confidentiality of its key resource library of chemicals.

The use of acute toxicology data deriving from direct exposure of this species is not indicative of true exposure under use and could cause undue alarm when presented out of context.

7. If the information in question is "health and safety data" pursuant to 40 CFR part 2.306 (3) (i), do your assert that disclosure of the information you are claiming confidential would reveal:

- confidential process information;
- confidential portions of a mixture; or
- information unrelated to the effects of the substance on human health or the environment?

Aside from the chemical structure and name this submission does not reveal any information related to the process, product composition or other information unrelated to human health effects or the environment.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

H. Michael D. Utidjian, M.D.
Corporate Medical Director
American Cyanamid Company
One Cyanamid Plaza
Wayne, New Jersey 07470

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 24 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and **refer to the reverse side of this page for "EPA Information Requests"**.

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 13301A

Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP CAP

Submission number: 13301A

TSCA Inventory: Y N ?

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Erlie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** — **pages** 1

Notes:

Contractor reviewer : TDL **Date:** 4/21/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 0195-13301 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: American Cyanamid Company

SUB. DATE: 12/27/94 OTS DATE: 01/03/95 CSRAD DATE: 02/24/95

CHEMICAL NAME: Azoxycyanide, substituted

CAS#: Confident

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER BENEFITS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RBT	LOW	R & D	
CAS SR	NO	NO (CONTINUE)		MED	fungicide	
	(IN INVENTORY)	REFER		HIGH		

COMMENTS: Non-CAP

13301A

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Eye irritation in rabbits is of high concern. Instillation of 100 mg of the substance into one eye of two rabbits without washing resulted in corrosion within 72 hours.